IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

POLYSCIENCES, INC.	

Plaintiff, : Civil Action No. 20-cv-03649-PBT

JOSEPH T. MASRUD,

v.

Defendant.

DECLARATION OF JOSEPH T. MASRUD
IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING
ORDER AND PLELIMINARY INJUNCTION

I, Joseph T. Masrud, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

- 1. I am over 21 years of age and am a resident of the State of Minnesota. I am competent to execute this Declaration and have personal knowledge of the matters set forth herein.
- 2. I submit this declaration in opposition to Polysciences' motion for a temporary restraining order and preliminary injunction ("Motion"). Based on the facts set forth herein, and the accompanying Memorandum of Law, I respectfully request that this court deny Polysciences' request for a temporary restraining order and/or preliminary injunction.
- I have a Bachelor of Science degree in Chemistry from the University of Minnesota and a Master of Business Administration degree from Case Western Reserve University.
- 4. I was hired by Polysciences in January 2014, as a Business Development

 Manager in the Lab Products Group. I was subsequently promoted to Business Manager and

then to Director. In these roles I was responsible for sales and marketing of Polysciences' laboratory products.

5. Polysciences is a chemical manufacturing company that produces and sells a broad array of products for both industrial and scientific uses. One of their products is Polyethylenimine ("PEI"), which is a chemical that has been used for decades for many industrial uses (e.g. in detergents, adhesives, as a water treatment agent, and in cosmetics) and in bioprocessing as a chemical transfection reagent.

History of PEI and its Use as a Transfection Reagent

- 6. Instructions to make PEI have been publicly available since 1983. See **Exhibit** "A" (Ryuichi Tanaka et al., *High Molecular Weight Linear Poly(ethylenimine) and Poly(N-Methylenimine)*, Macromoleculates, June 1, 1983 at 849-853).
- 7. From July 7, 1995 through July 7, 2015, Polyplus-transfection SA ("Polyplus"), a French company, held a "use patent" for the use of PEI as a transfection agent. **Exhibit "B"** (Patent No. US6013240A, Application USO8/765,679). A use patent provides protection to a company who discovers that a patented product can be used for a purpose that is different from what the patent owner contemplated.
- 8. When used as a transfection reagent, PEI facilitates inserting DNA into cells to study the function of genes or gene products, and is used to develop new drugs and gene therapies for life-saving medical procedures.
- 9. It was only beginning in 2015 that companies besides Polyplus could sell PEI for use as a transfection agent.
- 10. Numerous articles were published prior to Polyplus' use patent expiring, about how to prepare PEI specifically as a transfection reagent. By way of example only, *see*, *e.g.*,

Exhibit "C" (Abdennaji Adib et al., Method for Manufacturing Linear Polyethylenimine (PEI) for Transfection Purpose and Linear PEI Obtained with Such Method," August 5, 2010, patents.google.com/patent/US2010019788A1/en); Exhibit "D" (Blandine Brissault et al., Synthesis of Linear Polyethylenimine Derivatives for DNA Transfection," Biconjugate Chem. 2003,14, 3, 581-587 (May 1, 2003); Exhibit "E" (Ji Hoon Jeong et al., DNA Transfection Using Linear Poly(Ethylenimine) Prepared by Controlled Acid Hydrolysis of Poly(2-Ethyl-2-Oxazoline, Journal of Controlled Release Vol. 73, Issues 2-3, pp. 391-399, June 15, 2001); Exhibit "F" (Mini Thomas et al., Full Deacylation of Polyethylenimine Dramatically Boosts Its Gene Delivery Efficiency and Specificity to Mouse Lung, Proceedings of the National Academy of Science, April 19, 2005, 102(16) 5679-5684); Exhibit "G" (Van Kuringen et al., Partial Hydrolysis of Poly(2-ethyl-2-Oxazoline) and Potential Implications for Biomedical Applications?, Macromolecular Bioscience Vol. 12, Issue 8, pp. 1114-1123 (August 2012), first published July 6, 2012); Exhibit "H" (Ren-Hua Jin and Jian Jun Yuan, Hierarchically Structured Silica from Mediation of Linear Poly(ethyleneimine) Incorporated with Acidic/Basic Additives. Polymer Journal Vol. 39, Issue 5, pp. 464-470 (April 2007); Exhibit "I" (Laurence Delafosse, et al. Comparative Study of Polyethylenimines for Transient Gene Expression in Mammalian HEK293 and CHO Cells, Journal of Biotechnology, Vol. 227, pp. 103-111, June 2016; Exhibit "J" (Zuzana Kadlecova, et al. Poly(Ethyleneimine)-Mediated Large-Scale *Transient Gene Expression: Influence of Molecular Weight, Polydispersity and N -Propionyl* Groups. Macromolecular Bioscience, Vol. 12, No. 5, pp. 628-623, May 2012). See also Exhibit B (Polyplus use patent), which is yet another public source for information about using PEI for transfection, and shows multiple molecular weights of PEI that are effective for transfection as well as how to use PEI in gene transfection. *Id.* at p. 1 (claim 5) and 7 (Example 10).

- 11. In addition, the qualitative molecular weight distribution of Polysciences' PEI Max is also publicly available. **Exhibit "K."**
- 12. The manufacture of PEI transfection reagents is not difficult. There are four ingredients or raw materials: (1) Pol(2-ethyl-2-oxazoline) ("PEOx"), (2) water; (3) hydrochloric acid ("HCI"), and (4) a wash solvent. *See, e.g.*, Exhibit "D" at pp. 1, 2; Exhibit "E" at p. 2; Exhibit "F" at pp. 1, 2; Exhibit "G" at p. 2, 3; Exhibit "H" at p. 2.
- 13. The primary ingredient is PEOx. Contrary to Polysciences' motion, the source and price of PEOx is no secret, and can easily be found on-line. See, e.g. **Exhibit "L"** (compilation of website pages identifying sources and prices for PEOx). Distilled water, HCl, and wash solvents can also be easily sourced through internet searches for suppliers.
- 14. As explained in the publications cited in this Affidavit, you simply mix the three ingredients in specified amounts and heat the mixture to near boiling for at least several hours, which forms a wet mixture of PEI, HCl, and water. You then remove residual acid and water from the wet PEI mixture and are left with PEI powder. Exhibit "D" at p. 2; Exhibit "E" at p. 2, Exhibit "F" at p. 2; Exhibit "G" at pp. 3; Exhibit "H" at p. 2.
- 15. All of this can be accomplished using standard equipment. Time, temperature, concentration of water and acid can be tweaked until you reach the desired results.

Polyscience's PEI Transfection Reagent Product Offerings

16. Polysciences had been manufacturing and selling PEI products for years prior to my hire in 2014. Those products included (1) Linear PEI MW 25,000 (PN23966) and (2) PEI MAX®, MW 40,000 HCl salt (PN 24765) ("PEI Max"), both of which are a powder, and both of which could be used for industrial or transfection purposes. Because transfection requires PEI to

be in liquid form, PEI Max was more suitable as a transfection agent because it dissolves easier in water.

- 17. When Polyplus' use patent expired in July 2015, I was involved in the decision to specifically market Polysciences' PEI products as a transfection reagent to be used in the research and development ("R&D") of drug and gene therapies.
- Once Polysciences was able to market its PEI for transfection, it offered its customers the option to buy it in powder form (PEI Max/Linear PEI) or a "ready to use" liquid form. The liquid "ready to use" versions were sold under the "Transporter" mark [(1) Transporter 5TM Transfection Reagent 5 ml (PN 26008-5) and (2) Transporter 5TM Transfection Reagent 50 ml (PN 26008-50)], both of which were based on Polysciences' PEI Max.
- 19. Contrary to Polysciences' suggestion otherwise, the process of transforming the PEI powders into liquid form is not a trade secret. The instructions to do so are available on Polysciences website, and throughout my tenure with Polysciences it readily gave these instructions to actual and prospective customers in the event that they preferred to buy the less expensive powder and transform it themselves into a liquid. **Exhibit "M"** (24765_usage_guide.pdf, downloaded from Polysciences website on August 4, 2020 at https://www.polysciences.com/skin/frontend/default/polysciences/pdf/24765_usage_guide.pdf).
- 20. The instructions for this process are also available through additional public means. See, e.g. Exhibit "N" (Patti A. Longo, et al., Transient Mammalian Cell Transfection with Polyethylenimine (PEI), Methods in Enzymology, Vol. 529, pp. 227-40 (2013)) at p. 3; Exhibit "O" (Martin S. Taylor, et al., Characterization of L1-Ribonucleoprotein Particles." Transposons and Retrotransposons, Vol. 1400, pp. 311–313, Springer New York (2016)) at p. 4;

Exhibit "P" (Yong Hong Chen, et al. *Adeno-Associated Virus Production, Purification, and Titering*, Current Protocols in Mouse Biology, Vol. 8, No. 4, p. e56, Dec. 2018) at p. 10.

- 21. At all times during my tenure with Polysciences, and to date, Polysciences publishes the price at which it sells the aforementioned PEI products. *See, e.g.* Exhibit "Q" (Polysciences website pages recovered from web.archive.org showing price of PEI Max on May 9, 2019 and Transporter 5 on December 4, 2018); Exhibit "R" (Polysciences website pages dated respectively August 5, 2010 and August 4, 2020 showing current price of PEI Max and Transporter 5 respectively at https://www.polysciences.com/default/catalog-products/life-sciences/transfection-reagents/polyethylenimine-max-mw40000-high-potency-linear-pei/ and https://www.polysciences.com/default/transporter-5-transfection-reagent).
- 22. Polysciences eventually created a PEI powder and liquid transfection reagent (similar to PEI Max and Transporter 5) through a "Good Manufacturing Practice" ("GMP") compliance process, creating a MAXgeneTM GMP powder and liquid that it could market and sell for use in clinical trials and the commercial manufacturing of drugs and gene therapies.
- 23. Polysciences did not sell any GMP products prior to the termination of my association with the company, nor did it set a price for the GMP products during my tenure.

Termination of Polyscience's Employment/Consulting Relationship

- 24. In or about January 2019, I informed Polysciences that I intended to move from Philadelphia (where Polysciences is based) to Minnesota, and requested to work for Polysciences remotely. My last date of employment with Polysciences was June 26, 2019.
- 25. Polysciences hired me as a consultant on or about July 1, 2019, and agreed to an initial term through December 30, 2019, to be renewed automatically each year for a one-year term upon mutual agreement.

- 26. I formed Serochem LLC in June 2019, through which to consult for Polysciences and to potentially develop bioprocessing products and services that I could sell through Polysciences.
- 27. I emailed the "Polysciences PEI Quality Guide" to myself on August 20, 2019, when I was a consultant working remotely for Polysciences, to make edits to the document from my home computer.
- 28. While Polysciences claims in its Motion that the "Polysciences PEI Quality Guide" was a "unique compilation of data that Polysciences has maintained as a trade secret[,]" in actuality it was a document that was intended to be provided to existing and potential customers (irrespective of the existence of a non-disclosure agreement) to help them decide which PEI product to select for their purpose. In addition, the information identified on the Guide was not treated by Polysciences as confidential during my tenure, as evidenced by the following:
- a. Product specifications for products within the Lab Products group at Polysciences were freely provided upon request to potential and existing customers.
- b. Polysciences published a Certificate of Analysis for a batch of PEI Max on its website which provides product specifications and the test results, and it may have published others. *See, e.g.,* **Exhibit "S"** (Polysciences website page, Certificate of Analysis for Polyethyleneimine 'Max'(40 000m.W. Linear, Lot 706510 at https://www.polysciences.com/skin/frontend/default/polysciences/pdf/24765_exca.pdf);
- c. Polysciences publishes a Transporter 5 Flyer that contains additional marketing information regarding Transporter 5 including the performance specification (IgG Expression) that Polysciences now appears to claim is confidential. **Exhibit "T"**

- d. Polysciences publishes the heavy metal specifications for MAXgene on its website. *See, e.g.*, **Exhibit "U"** (MaxGene GMP Product page published on Polysciences website at https://www.polysciences.com/skin/frontend/default/polysciences/pdf/MAXgene.pdf).
- 29. Since the conclusion of my consultancy with Polysciences, I have not used or disclosed the Polysciences PEI Quality Guide, or the information contained therein, for any purpose.
- 30. At no time following the termination of my employment with Polysciences in June 2019, or the conclusion of my consultancy with Polysciences in September 2019, did anyone from Polysciences request that I return any information (other than the company laptop and badge) to Polysciences or request that I return and/or destroy any electronic information that may have remained in my possession.
 - 31. On September 6, 2019, Polysciences terminated my services.
- 32. Polysciences did not sell any GMP products prior to the termination of my association with the company.

Serochem's Development of PEI Transfection Products

- 33. Shortly after Polysciences terminated my consulting agreement, Serochem began the process of researching and developing its own non-GMP non-medical grade PEI transfection products in powder (PEI Prime Powder) and a liquid form (PEI Prime AQ) to be used in R&D applications.
- 34. Serochem used only publicly available information and general chemistry and biology knowledge, including publications attached to this Declaration to develop Serochem's products.

- 35. Serochem launched its PEI Prime Powder for sale on its website on June 7, 2020, and launched PEI Prime AQ sometime between June 8, 2020 and June 12, 2020.
- 36. While Serochem's products compete with Polysciences' PEI Max and Transporter 5 products, they are not identical. Performance testing by a third-party testing facility demonstrates, for example, that Serochem's PEI Prime performed statistically different from and, on average 48% better than, PEI Max in HEK293 cells. **Exhibit "V"** (Serochem HEK293 Performance Data published on the Serochem website at https://www.serochem/post/pei-prime-performance-datea-hek293).
- 37. The fact that Serochem recommends not to freeze PEI Prime solution formulated from the powder, and to store the formulated solution at 4° C for 6 months, does not, as Polysciences' asserts, suggest that Serochem used Polysciences' confidential information.
- 38. PEI solution storage conditions (refrigerate don't freeze) are not confidential or proprietary. Not only has Polysciences published the storage recommendations of PEI Max on its own website, many publications also explicitly state that Polyscience's PEI Max solutions should be refrigerated, not frozen. *See, e.g.*, **Exhibit "W"** (Printout dated Aug. 4, 2020 from Polysciences website, https://www.polysciences.com/default/transporter-5-transfection-reagent), stating "Storage: Store at 4 °C; do not freeze"; Exhibit "N" at p. 3 noting that PEI is "Stable at least 9 months at 4 °C" and that "PEI 'Max' cannot be frozen!"); Exhibit "N" at p. 4 stating with respect to the storage of a PEI Max solution "store at 4 °C. NEVER FREEZE PEI working stock. Working stocks can be used for up to 6 months if stored at 4 °C."
- 39. In an effort to support myself and my family, I have invested a significant portion of my savings to get Serochem off the ground.

¹ 4° C represents the standard temperature for refrigeration.

40. To date, Serochem has earned under \$600 from the sale of its PEI products.

Dated: August 27, 2020

Joseph T. Masrud